K022079

P. 1/2

SEP 24 2002

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Telephone: (574) 372-1644
Fax: (574) 372-1683

Proprietary Name: Short and Long Soft Tissue Attachment Sleeve

Common Name: Short and Long Soft Tissue Attachment Sleeve

Classification Name: Prosthesis, shoulder non-constrained, metal / polymer cemented (21 CFR 888.3650)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1. LIMA RPS Shoulder (K913282)
2. Biomet Modular Proximal Humeral Replacement System (K020045), now known as the Mosaic™ Humeral System

Device Description: This particular design utilizes a taper junction between the sleeve and the segment component of the Biomet Proximal Humeral Replacement System (K020045). For secure placement, the sleeve has a larger proximal taper junction. Because the soft tissue will naturally be pulling proximally, if the taper junction does move, the soft tissue will only tighten the taper.

There are two sizes that vary only in length and suture hole availability. The short sleeve has 4 suture holes available and the holes are arranged perpendicular to the axis of the segment. The long sleeve has 5 suture holes that are arranged perpendicular to the axis of the segment and 4 suture holes placed parallel to the axis of the segment. Both sleeves have the same outside and inside diameters and inside mating taper.

The sleeves are designed for use in conjunction with the Biomet Modular Proximal Humeral Replacement System (K020045), now called the Mosaic™ Humeral System to provide the option for soft tissue stabilization and attachment to the prosthetic device

Indications:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis
3. Revision where other devices or treatments have failed
4. Correction of functional deformity
5. Treatment of acute fracture of the humeral head unmanageable using other treatment methods.

The sleeves can be used for oncology applications.

The sleeves are designed for use with the Biomet Modular Proximal Humeral Replacement System (K020045), now called the Mosaic™ Humeral System to provide the option for soft tissue stabilization and attachment.

The Biomet Proximal Humeral Replacement System (K020045) is for use with bone cement.

Summary of Technologies:	The Short and Long Soft Tissue Attachment Sleeve components (materials, design, sizes and indications) are similar or identical to the predicate devices.
Non-Clinical Testing:	Mechanical testing with Engineering Justifications determined that the Short and Long Soft Tissue Attachment Sleeve components presented no new risks and were therefore, substantially equivalent to the predicate device.
Clinical Testing:	No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2002

Ms. Kacy Arnold, RN, MBA
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K022079
Trade/Device Name: Short and Long Soft Tissue Attachment Sleeves
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT
Dated: June 14, 2002
Received: June 26, 2002

Dear Ms. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If known): K022079

Device Name: Short and Long Soft Tissue Attachment Sleeves

Indications for Use:

The indications for the use of the Short and Long Soft Tissue Attachment Sleeves include:

1. Non-Inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2. Rheumatoid arthritis
3. Revision where other devices or treatments have failed
4. Correction of functional deformity
5. Treatment of acute fracture of the humeral head unmanageable using other treatment methods

The sleeves can be used for oncology applications.

The sleeves are designed for use with the Biomet Mosaic™ Humeral System (K020045), to provide the option for soft tissue stabilization and attachment.

The Biomet Mosaic™ Humeral System (K020045) is for use with bone cement.

for Mark N Milleson

(Division Sig
Division of G Restorative
and Neurologi ices

510(k) Number K022079

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)